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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,639	06/28/2005	Jason Fong	50164/015002	3127

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EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,639	FONG ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *15 Mar 06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 33-51 are examined.

Applicant has amended claims 33, 42-45 and 49-50 and provided arguments for the patentability of claims 33-51 in the response filed 15 March 2006.

Applicant's arguments, see response, filed 15 March 2006, have been fully considered and are persuasive to the extent that the objection of claim 33 and the rejection of claims 43-44 and 49-50 under 35 USC §112, have been withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 33-38 and 40-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,073,922 to Wyburn-Mason in view of ADAP Drugs: http://www.aegis.com/factshts/network/access/drugs/clot.html Last modified 26 June 1996. Retrieved 9 November 2005 and further in view of PDR ® Electronic Library http://www.thomsonhc.com/pdrel/librarian/ND_PR/Pdr/SBK/2/PFPUI/Ao4T53O11Yyld7/ND_PG/SearchBreadCrumbPrintReady/ND_CP/Pdr/CS/C24210/ND_CPR/KeywordSearch/ND_T/PDRel/ND_P/PdrStedmanHerbal/DUPLICATIONSHIELDSYNC/67663A/ND_

B/PDRel/PFFormActionId_pdrcommon.BrandAction/null/SBK/2?ContentDesc=Hydrocortone+Tablets&DocumentDefinition=pdrcommon.Pdr&DocumentId=52401914 Issued November 2001. Retrieved 9 November 2005.

Wyburn-Mason teach a method of treating rheumatoid arthritis (in current claim 1; see Abstract) with a compound such as clotrimazole (in current claims 37-38, 45, 51; see Abstract and col 5 lines 30-31) comprising a pharmaceutically acceptable carrier (in current claims 46, 51; see col 6 lines 50-53) and further teaches that cortisone and corticosteroids have been commonly used in treating rheumatoid arthritis (in current claims 33, 40-42, 45-46, 51; see col 1 lines 38-41).

Wyburn-Mason does not teach a method wherein the azole and steroid are administered 24 hours apart or 14 days apart for example, nor does Wyburn-Mason recite the specific corticosteroids applicant claims or the low dosage claimed.

http://www.aegis.com/factshts/network/access/drugs/clot.html teaches that clotrimazole is sold as 10mg lozenges (in current claims 43-44 and 47-50; see Dosage) and the PDR teaches that hydrocortisone is supplied in 10mg dosages (in current claims 44 and 47-48, 50 see page 1 of 1).

One of ordinary skill in the art would have appreciated and been able to see from the teaching in Wyburn-Mason that glucocorticoid or mineralocorticoid would have been an obvious corticosteroid particularly because Wyburn-Mason teach that there are a plurality of corticosteroids that are used as rheumatoid arthritis treatments (see col 1 lines 40-41: "Chemical compounds which have been commonly used in treating rheumatoid arthritis are corticosteroids,...")

One of ordinary skill in the art would have appreciated the use of both an azole, such as clotrimazole, and a steroid, such as a corticosteroid, since both have been traditionally used to treat rheumatoid arthritis. That the azole and corticosteroid are used separately is not a patentable feature of the claim since people suffering from rheumatoid arthritis have been using both treatments separately for example if one treatment fails or the condition is not ameliorated with only one treatment. One of ordinary skill in the art would also appreciate the obviousness of combining two treatments for the same indication wherein the treatments have a different mechanism of action thereby treating the indication via separate pathways such that the treatment has more than an additive affect on a patient. Further, combining agents which are known to be useful to treat rheumatoid arthritis individually into a single composition useful for the very same purpose is prima facie obvious. See In re Kerkhoven 205 USPQ 1069. Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining an azole and a steroid flows logically from their having been individually taught in the prior art.

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Wyburn-Mason with the PDR and ADAP since the PDR and ADAP are provided to show the current state of the art at the time the application was filed as well as the dosage availability of the compositions. Specifically, the PDR is a reference document for physicians and is commonly used to

show the current availabilities of pharmaceuticals on the market and that ADAP is another resource guide for pharmaceuticals. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 33-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,073,922 to Wyburn-Mason in view of ADAP Drugs: http://www.aegis.com/factshts/network/access/drugs/clot.html Retrieved 9 November 2005 as applied to claims 33-38 and 40-51 above and further in view of PDR ® Electronic Library http://www.thomsonhc.com/pdrel/librarian/ND_PR/Pdr/SBK/2/PFPUI/Ao4T53O11Yyld7/ND_PG/SearchBreadCrumbPrintReady/ND_CP/Pdr/CS/C24210/ND_CPR/KeywordSearch/ND_T/PDRel/ND_P/PdrStedmanHerbal/DUPLICATIONSHIELDSYNC/67663A/ND_B/PDRel/PFFormActionId_pdrcommon.BrandAction/null/SBK/2?ContentDesc=Hydrocortone+Tablets&DocumentDefinition=pdrcommon.Pdr&DocumentId=52401914 Retrieved 9 November 2005 as applied to claims 33-38 and 40-51 above and further in view of US Patent No. 6,545028 to Jensen et al.

Jensen et al. teach the treatment of inflammatory disorders such as rheumatoid arthritis (in current claim 39; see col 13 line 5) with a triazole such as fluconazole (in current claim 39; see col 7 lines 45-60).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine the above references with Jensen et

al. because Jensen et al. is cited by Wyburn-Mason. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Response to Arguments - 35 USC §112

Applicant's arguments filed 15 March 2006 have been fully considered and are persuasive for the reasons of record.

Response to Arguments- 35 USC §103

Applicant's arguments filed 15 March 2006 have been fully considered but they are not persuasive. Applicant argues that the effect of combining the claimed actives is synergistic and to the extent that in vitro results demonstrate such synergy, the Applicant provides data in the Specification. Nonetheless, a showing of unexpected results in vitro cannot overcome a rejection of obviousness in the case here where the breadth of the claim includes the treating of a patient. In addition, Wyburn-Mason specifically teach that corticosteroids are used for the treatment of RA (see rejection above) and for that reason, teach and/or suggest a combination of agents. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7 June 2006
MG

Ardin H. Marschel 6/11/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER